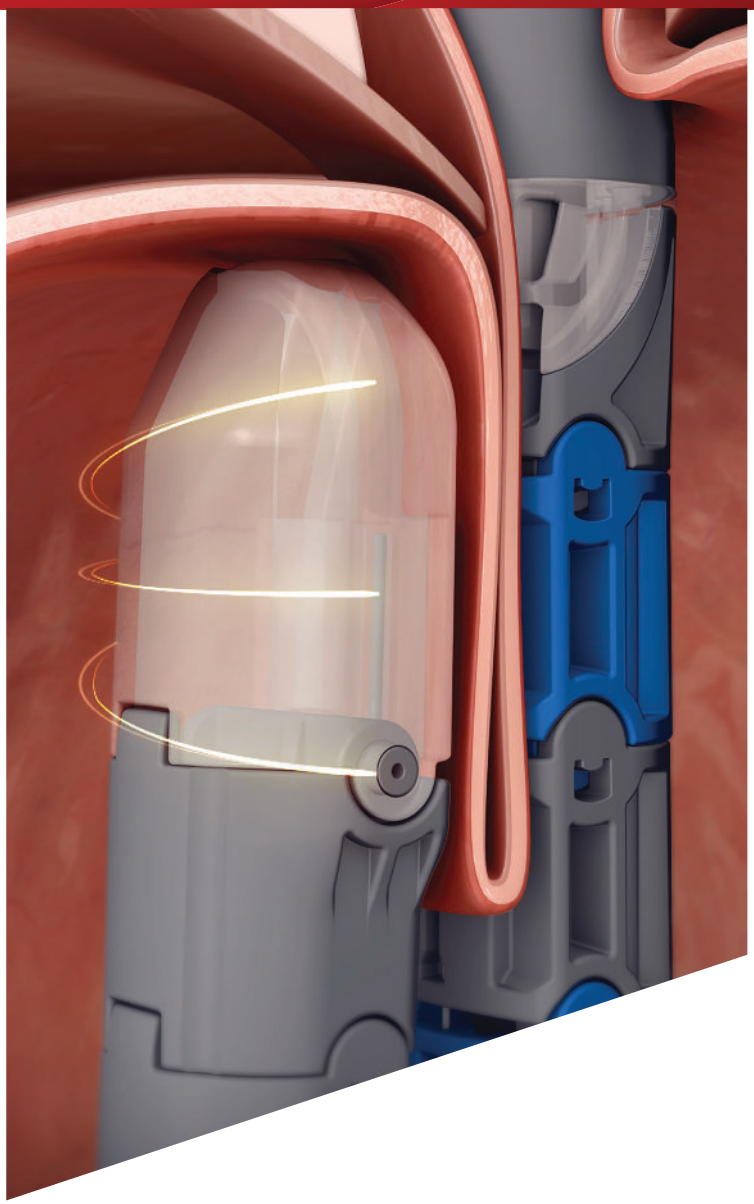
MERIT MEDICAL
ENDOTEK

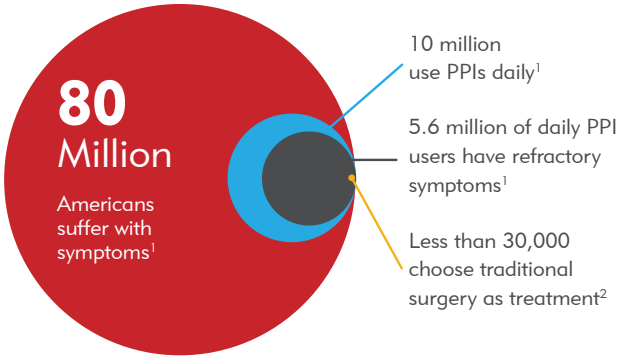


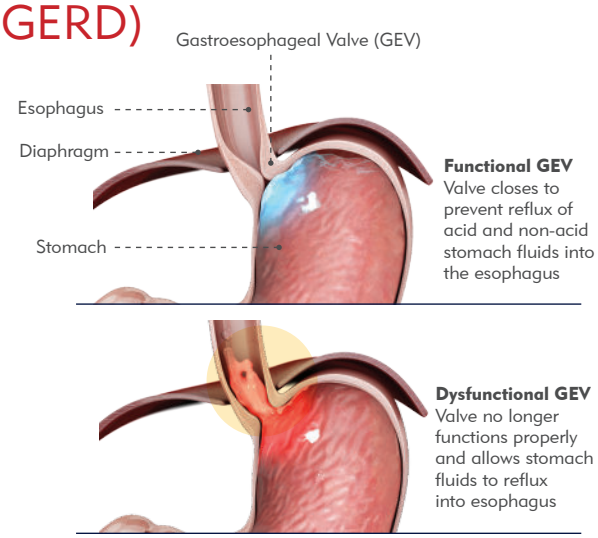
TIF® PROCEDURE
WITH Esophyx® Z+ DEVICE

CREATING THE Optimal AntiReflux Barrier

TIF 2.0® – An Innovative and Advanced Procedure for Treating Chronic GERD

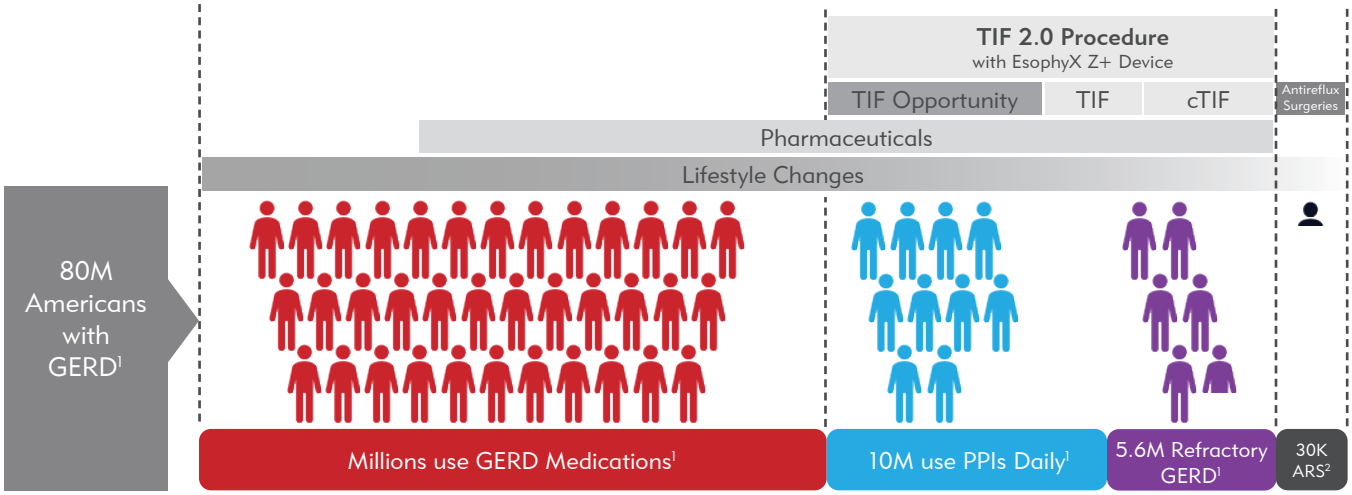
Gastroesophageal Reflux Disease (GERD)



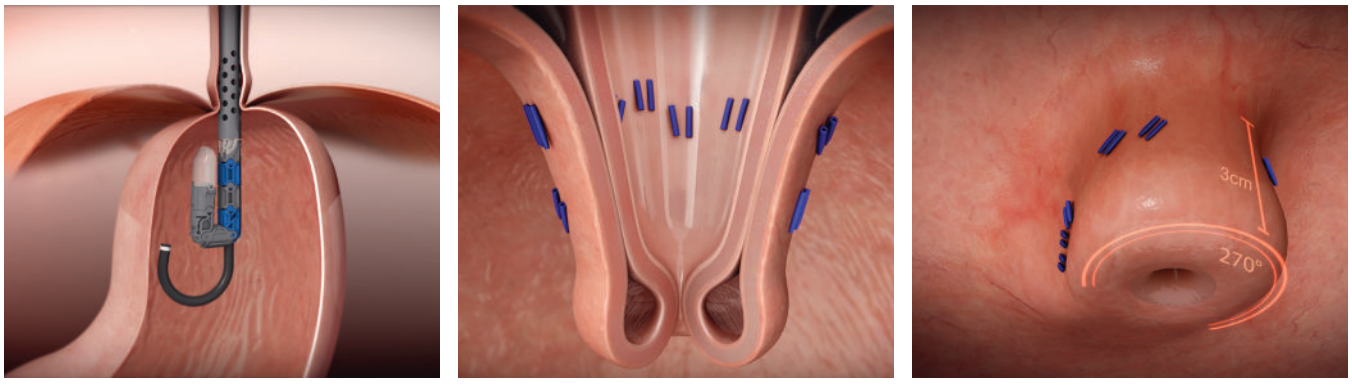


Most patients treat their GERD with over-the-counter or prescription medications - most frequently proton pump inhibitors (PPIs). With approximately 10 million patients on PPIs daily, over 50% are refractory and still experience symptoms.[1] Patients are increasingly interested in long-term solutions that improve symptoms and reduce medication dependency. The TIF 2.0 procedure bridges the gap between pharmacological therapies and traditional antireflux surgery, while providing faster recovery and fewer side effects than the conventional surgical options available to GERD patients today.[3]

TIF 2.0 Addresses the GERD Treatment Gap



Transoral Incisionless Fundoplication (the TIF 2.0 procedure) uses an endoscopic approach to restore anatomy and reconstruct the gastroesophageal valve (GEV) following the principles of traditional fundoplication with minimal side-effects.[3]



TIF 2.0 Creates the Optimal AntiReflux Barrier and Restores Anatomy to its Natural State[3]

During the procedure, the EsophyX® Z+ device is used to perform a series of plications that recreate the dynamics of the Angle of His and restore the gastroesophageal valve (GEV). By building the GEV around the EsophyX Z+ device, TIF 2.0 provides a reproducible and standardizable fundoplication. The result is a 270-degree omega-shaped valve that is approximately 3 cm in length, depending on the patient's anatomy.

- 270° anterior and posterior wrap recreates the Angle of His
- Lesser curvature of the stomach is preserved, reducing likelihood of side effects
- Approximately 3 cm valve length
- Reinforced with 20+ full thickness SerosaFuse® Fasteners to evenly distribute force
- No twisting or torquing of gastric folds

For patients with a hiatal hernia greater than 2cm, TIF 2.0 can be performed consecutively with a surgical hiatal hernia repair (cTIF®). Learn more about the cTIF procedure.

TIF 2.0 Follows the Principles of Traditional Fundoplication with Fewer Side Effects than Conventional AntiReflux Surgery[3]

	TIF 2.0/cTIF Procedure	Laparoscopic Fundoplication
Reduce hiatal hernia ≤ 2 cm (TIF 2.0)	✓	✓
Repair hiatal hernia › 2 cm and close crura[6] (cTIF)	✓	✓
Elongate the intrabdominal esophagus	✓	✓
Fundoplication	✓	✓
Approximate and tighten the fundus around the distal esophagus	✓	✓
Recreate the dynamics of the angle of His	✓	✓
Restore the distal high pressure zone	✓	✓

TIF 2.0 Patients Experience Fewer Side Effects[3]

NO Dysphagia

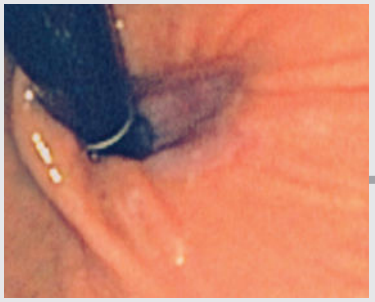
NO Increased Bloating

NO Increased Flatulence

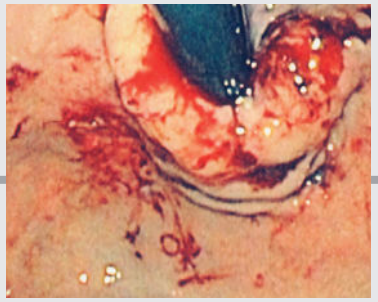
TIF 2.0 Provides Durable Relief for GERD Patients[4]

Date of TIF 2.0 procedure

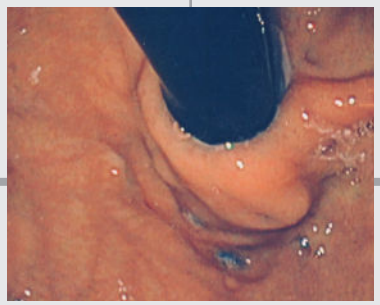
Five Years Post TIF 2.0 procedure



EGD at the start of TIF 2.0 procedure



EGD after completion of TIF 2.0 procedure



"This patient reports his symptoms are completely controlled and he remains off PPIs five years after the TIF procedure."
Peter Janu, M.D., Chilton, WI

TIF 2.0 Is Backed by Strong Clinical Evidence[5]

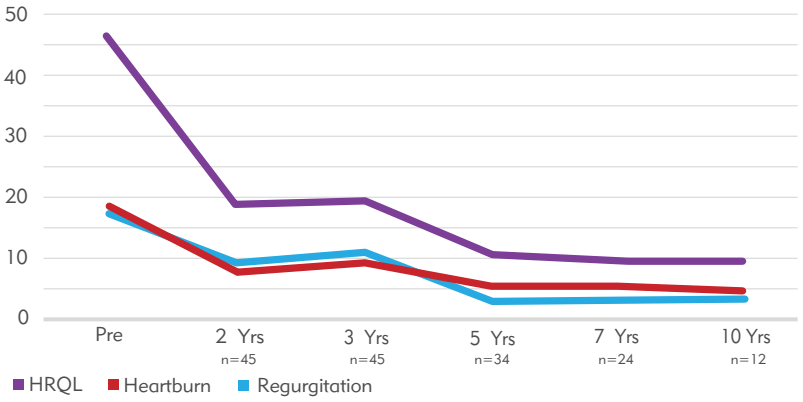
83%
of patients did not use daily PPIs one year post TIF 2.0[6]

79%
of patients were satisfied with their health condition one year post TIF 2.0[7]

77%
Esophagitis healed in 10 of 13 patients six months post TIF 2.0[8]

80%
of patients experienced sustained elimination of atypical symptoms five years post TIF 2.0.[6]

TIF 2.0 is Durable up to 10 Years[9]



35,000+	1,500	100+	4	Cat 1
procedures worldwide since original EsophyX® device clearance in 2007[10]	unique patients studied in 75 centers with consistent outcomes[5]	peer-reviewed clinical papers in respected gastroenterology and surgical journals in the past 12 years[5]	published randomized controlled trials; two with sham-controlled arms[5]	CPT® Code Esophagogastric Fundoplasty Trans-Orifice procedures effective 1/1/2016[5]

INDICATIONS
The Merit Medical Systems EsophyX Z+ Device with SerosaFuse® Fastener and accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2 cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.

REFERENCES
1. Delshad SD, et al. Prevalence of Gastroesophageal Reflux Disease and Proton Pump Inhibitor-Refractory Symptoms. Gastroenterology. 2020 Apr;158(5):1250-1261.e2. doi: 10.1053/j.gastro.2019.12.014. Epub 2019 Dec 19. PMID: 31866243. **2.** Finks JF, Wei Y, Birkmeyer JD. The rise and fall of antireflux surgery in the United States. Surg Endosc. 2006 Nov;20(11):1698-701. doi: 10.1007/s00464-006-0042-3. Epub 2006 Sep 6. PMID: 16960665. **3.** Janu P, Shughoury AB, Venkat K, et al. Laparoscopic Hiatal Hernia Repair Followed by Transoral Incisionless Fundoplication With EsophyX Device (HH + TIF): Efficacy and Safety in Two Community Hospitals. Surgical Innovation. 2019;26(6):675-686. doi:10.1177/1553350619869449. **4.** Trad KS, Barnes WE, Prevou ER, et al. The TEMPO Trial at 5 Years: Transoral Fundoplication (TIF 2.0) Is Safe, Durable, and Cost-effective. Surgical Innovation. 2018;25(2):149-157. **5.** Merit Medical, data on file. **6.** Trad KS, Barnes WE, Prevou ER, et al. The TEMPO Trial at 5 Years: Transoral Fundoplication (TIF 2.0) Is Safe, Durable, and Cost-effective. Surgical Innovation. 2018;25(2):149-157. **7.** Canto, Marcia Irene et al. Outcomes of Transoral Incisionless Fundoplication (TIF 2.0): A Prospective, Multicenter Cohort Study in Academic and Community Practices (with video). Gastrointestinal Endoscopy, 16 Sept. 2024, https://www.giejournal.org/article/S0016-5107(24)03453-9/fulltext. **8.** Hunter JG, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. Gastroenterology. 2015 Feb;148(2):324-333.e5. doi: 10.1053/j.gastro.2014.10.009. Epub 2014 Oct 13. PMID: 25448925. **9.** Testoni S, Hassan C, Mazzoleni G, et al. Long-term outcomes of transoral incisionless fundoplication for gastroesophageal reflux disease: systematic-review and meta-analysis. Endosc Int Open. 2021;9(2):E239-E246. doi:10.1055/a-1322-2209 **10.** Merit Medical, data on file, through August 31, 2023

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

Merit Medical defines the term "cTIF" as a **consecutive** Transoral Incisionless Fundoplication which consists of a Hiatal Hernia Repair (HHR) followed by a Transoral Incisionless Fundoplication (TIF) procedure under a single anesthesia setting.

MERIT MEDICAL ENDOTEK®

www.merit.com

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
1.801.253.1600
1.800.35.MERIT

Merit Medical Europe, Middle East, & Africa (EMEA)
Amerikalaan 42, 6199 AE
Maastricht-Airport
The Netherlands
+31 43 358 82 22

Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+353 (0) 91 703 733

408122001_001 ID 102324